

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

SONG, YOON KI

2 Floor Geumha Building 645-5 Yeoksam-dong Gangnam-gu
SEOUL 135-910 Republic of Korea

PCT

REC'D 03 MAY 2005

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 18 APRIL 2005 (18.04.2005)

Applicant's or agent's file reference
pct-kiom

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/KR2004/003554

International filing date (day/month/year)

31 DECEMBER 2004 (31.12.2004)

Priority date(day/month/year)

06 FEBRUARY 2004 (06.02.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 35/78, A23L 1/29

Applicant

KOREA INSTITUTE OF ORIENTAL MEDICINE et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

YEO, Ho Sup

Telephone No. 82-42-481-5627



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/003554

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/003554

Box No. II Priority

1. ☐ The following document has not yet been furnished:

- ☐ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

When the International Search Report has been done, the priority date of 06 February 2004 is considered as a valid date. Otherwise, the document KR 2004-0108500 A, published on 24 December 2004, would become relevant.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/003554

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

☐ paid additional fees

☐ paid additional fees under protest

☐ not paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☐ not complied with for the following reasons:

Claims 4, 6, 10 and 12 concern a pharmaceutical composition, and claims 5, 7, 11 and 13 concern a functional food. Although the abovementioned claims are relevant to the composition comprising the same active ingredient, there is no technical relationship between a pharmaceutical composition and a functional food.

Hence, the application contains the following separate groups of inventions not so linked as to form a single general inventive concept (PCT Rule 13.1) :

i) Claims 1-4, 6, 8-10 and 12

ii) Claims 1-3, 5, 7-9, 11 and 13

4. Consequently, this opinion has been established in respect of the following parts of the international application :

☐ all parts.

☐ the parts relating to claims Nos. _____

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/KR2004/003554

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-13	YES
	Claims		NO
Inventive step (IS)	Claims	8-13	YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations :

The present invention relates to a composition for the prevention and treatment of diabetic complications or for the prevention of aging, comprising an extract of any one selected from Euphorbiae radix, gingered Magnolia bark, parched Puerariae radix and Glycyrrhizae radix, or a mixture of extracts from these herbal materials, or magnolol isolated from Magnolia bark as an active ingredient.

The following documents have been considered for the purpose of this Written Opinion :

D1 = Clin. Med. J. (Engl). 102(3), 203-6 (1989)

D2 = Zhongguo Zhong Yao Za Zhi, 14(9), 557-9, 576 (1989)

D3 = JP 03-068517 A (25. 03. 1991)

D4 = JP 63-104912 A (10. 05. 1988)

D5 = JP 07-017856 A (20. 01. 1995)

1) Novelty

D1 and D2 state that an extract of Glycyrrhizae radix has the inhibitory effect on rat lens aldose reductase. D3-D5 state that some compounds isolated from Glycyrrhizae radix inhibit the activity of aldose reductase.

However, they do not clearly describe the effect of an extract of Glycyrrhizae radix in preventing and treating diabetic complications or in preventing aging.

(Continued on Supplemental Sheet.)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/003554

Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
KR 2003-0039241 (KR 2004-0108500 A)	24/12/2004	17/06/2003	

The earlier application whose priority has been claimed in the present application is the document KR 2004-0008047 A filed on 06 February 2004. It does not disclose a composition for preventing or treating diabetic complications, comprising magnolol isolated from Magnolia bark. Therefore, the priority of claims 8-13 in the present application is not valid.

The document KR 2004-0108500 A was published on 24 December 2004, i.e. between the priority and filing dates of the present application. In case the priority of claims 8-13 in the present application is not valid, this document is relevant for assessing novelty and inventive step.

2. Non-written disclosures (Rule 43bis.1 and 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box V.

Therefore, the subject-matter of claims 1-13 can be regarded as novel (PCT Article 33(2)).

2) Inventive step

Claims 1-7 relate to a composition for the prevention and treatment of diabetic complications or for the prevention of aging, comprising an extract of any one selected from Euphorbiae radix, gingered Magnolia bark, parched Puerariae radix and Glycyrrhizae radix, or a mixture of extracts from these herbal materials as an active ingredient.

D1-D5 do not clearly indicate that an extract of Glycyrrhizae radix is effective for preventing and treating diabetic complications or for preventing aging. However, it is well known to the skilled person in the art that aldose reductase inhibitors are useful for treating various complications of diabetes and for preventing aging.

Therefore, the skilled man in the art would arrive at the subject-matter of claims 1-7 without the exercise of inventive skill. Consequently, the subject-matter of claims 1-7 is not considered to fulfil the requirement of inventive step (PCT Article 33(3)).

Claims 8-13 concern a composition for the prevention and treatment of diabetic complications or for the prevention of aging, comprising magnolol isolated from Magnolia bark as an active ingredient.

However, D1-D5 do not state that magnolol would be useful for preventing and treating diabetic complications or for preventing aging. Thus, the subject-matter of claims 8-13 is considered to involve an inventive step (PCT Article 33(3)).

3) Industrial applicability

Claims 1-13 meet the criteria set out in PCT Article 33(4).